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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,582	11/25/2003	Joseph F. Obermiller	PA-5213-CIP-CON	5774
7590	03/31/2005		EXAMINER	
Charles W. Agnew Registered Patent Agent P.O. Box 2269 Bloomington, IN 47402-2269			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/721,582

Applicant(s)

OBERMILLER, JOSEPH F.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-10,12 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of **Valve Prosthesis**: Species SR (Figures 48, 49), **Material of support frame**: Species A (wire), **Corners of support frame**: Species B (Figure 9), and **Attachment of biomaterial to itself**: Species C (heat source) in the reply filed on January 31, 2005 is acknowledged.

The traversal is on the ground(s) that “*Applicant regards the creation of these species groups as being unnecessary in order for the Examiner to conduct a reasonable search*” (see Response to Election of Species Requirement at page 2, first paragraph, lines 10-12). This is not found persuasive because the stent/graft art, the stent having valve means art, and the heart valve art are crowded arts. As defined in MPEP 808.01(a), for an Election of Species “*it is not necessary to show a separate status in the art or separate classification*”. Also, that same section of the MPEP teaches that for a multiplicity of species requiring extensive and/or burdensome search, “*a requirement for an election of species should be made prior to a search*”. Based on Applicant’s own admission that “‘welding’ can encompass both heat and pressure” (see Response to Election of Species Requirement at page 2, second paragraph, lines 4-5), any reference teaching heat and/or pressure will be interpreted as teaching welding as well (and vice versa).

Furthermore, the Office Action state: “*should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case*”.

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The requirement is still deemed proper and is therefore made FINAL.

2. Claims 2, 3, and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 31, 2005.

### *Specification*

3. The Brief Description of Drawings is objected to because of the following informalities:
  - a. There is no brief description of Figure 1A. Appropriate correction is required.

### *Drawings*

4. A first set (14 sheets) of formal drawings (including Figures 26 and 26A) was received on November 15, 2003. A second set (1 sheet) of formal drawings (including Figure 50) was received on June 7, 2004. These drawings are approved. Applicant is respectfully required to submit a new set of formal drawings that will include Figures 26, 26A, and 50 (as well as the requested corrections and additions requested on 11/15/2003) as part of the whole set of drawings (Figures 1-50).

### *Claim Objections*

5. Claim 13 is objected to because of the following informality: please substitute "outer wall-engaging edge" (see line 5) with --wall-engaging outer edge--. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding the limitation “is enclosed by at two layers of the biomaterial” (see lines 5-6) is vague and confusing, rendering claim 13 indefinite.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 4-10, 12, and 13 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by DiMatteo et al. (US 6,440,164 B1).

Referring to Figures 1-4 and 14-16, DiMatteo et al. disclose an expandable implantable vascular valve comprising: (i) a support frame (trellis 24 includes scaffold 30 and leaf frames 62); (ii) one or more leaflets (e.g., valve leaf cover 80; additionally, there is a first liner 82 comprising a webbing 84) comprised of a biomaterial (see list of materials disclosed in columns 10 and 11) attached to the support frame and *configured to function* (emphasis added to

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functional language) as a valve; and (iii) wherein the biomaterial is wrapped around the support frame and affixed to itself by heat setting, adhesive welding, application of uniform force (= pressure), and other bonding techniques (see column 11, lines 27-32), thereby securing the one or more leaflets to the support frame (see entire document). First liner 82 could comprise at least one flap 86 that folds over the support frame and is subsequently laminated to itself (see column 11, lines 15-20). First liner 82 could be laminated with second liner 88, therefore encasing all of trellis 24 or just scaffold 30 (see column 11, lines 21-27 and lines 32-35).

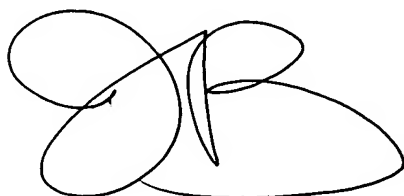
### *Conclusion*

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Love (US 6,494,904 B1) and Xie et al. (US 2003/0181974 A1).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



March 27, 2005

  
David H. Willse  
Primary Examiner